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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,010	08/06/2007	Paul Ross	9008-1004	8808

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
04/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/576,010	ROSS ET AL.	
	Examiner	Art Unit	
	DEBORAH K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-51* is/are pending in the application.

4a) Of the above claim(s) *28-44 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-51 are pending.

Response to Amendment

The amendment filed January 14, 2011, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The amendment has overcome the prior art rejection, however, a new search on the newly claimed invention has resulted in new art against the claims. Applicants did not previously claim a composition adapted for application to localized infection of the skin, nor did they claim an administering step to a localized infection of the skin. Also the new claims have prompted a new rejection under 35 USC 112, fourth paragraph, as well.

Election/Restrictions

Applicant's election with traverse of Group III in the reply filed on June 28, 2010, is acknowledged. The traversal is on the ground(s) that the claims have the same special technical feature. Note that claim 51, should actually be in Group I because it is dependent upon claim 28, thus, Group III encompasses claims 45-50. This is not found persuasive because claim 35 requires a supernatant of which Group III is carried out with a live probiotic and the methods of Groups I and II are directed to different methods of which one is directed to live probiotic specific strains and the other a supernatant. Further, specific PMN cells are stimulated by one Group and not the other. Thus, a reference which reads on Groups I or II will not necessarily read on Group III. However,

upon the indication of allowable subject matter it is possible that the claims will be rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-44 and 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 28, 2010.

Claim Rejections - 35 USC § 112

The following is a quotation of the fourth paragraph of 35 U.S.C. 112

"a claim in a dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" and requires the dependent claim to further limit the subject matter claimed."

Claim 47 fails to specify a further limitation of the subject matter of claim 46 and is, therefore, unpatentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45-47 and 49 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by newly cited Wynne et al (USP 7125708), see enclosed PTO-892 Form.

Claims are drawn to a pharmaceutical composition adapted for application to localized infection of the skin comprising a non-pathogenic culture of a probiotic and a pharmaceutically acceptable carrier and a method comprising administering to a localized infection of the skin of a subject, therefor.

Wynne et al teach a pharmaceutical composition adapted for application to localized infection of the skin comprising a non-pathogenic culture of a probiotic (col. 4, lines 24-25, 55-65 and 33 and col. 5, lines 1-20 and a pharmaceutically acceptable carrier (col. 4, lines 31-33) and a method comprising administering to a localized infection of the skin (urinary tract) of a subject, therefor, col. 4, line 2.

The claims are identical to the disclosure teachings of Wynne et al and are, therefore, considered to be anticipated by the teachings of Wynne et al.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 46 and 48 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Glenn et al (USPUB 20020159976), cited on enclosed PTO-892 Form.

Claims are drawn to method of treating a subject having the infectious disease localized to an infected wound, comprising using a composition comprising a nonpathogenic probiotic.

Glenn et al teach a method of treating a subject having the infectious disease localized to an infected wound, comprising using a composition comprising a nonpathogenic probiotic, note page 123, col. 2, lines 30-35.

The claims are identical to the disclosure teachings of Glenn et al and are, therefore, considered to be anticipated by the teachings of Glenn et al.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Mollett et al (USP 5756665), see enclosed PTO-892 Form.

Claims are discussed above.

Mollett et al teach that similarly to the invention of Mollett et al, a bacteriocin has been isolated from Lactococcus lactis note col. 1, lines 30-35. Mollett et al teach a bacteriocin which is isolated from supernatant of a probiotic microorganism, note col. 1,

lines 10-15 and col. 2, lines 20-25 and 30-36. Furthermore, the supernatant or probiotic are useful for treating pathogenic bacteria of the skin, note col. 5, lines 23-25.

Claims are identical to the disclosure of Mollett et al and are considered, therefore, to be anticipated by the teachings of Mollett et al. The carrier is present in the composition because the probiotic is in the form of creams or powders. Thus, the carrier is inherent in the composition and must be, therefore, a pharmaceutically acceptable carrier or diluent. Also the micoorganism is disclosed to be food grade and is applicable to the skin to combat pathogenic bacteria of the skin of which is inherently present in an infectious disease localized to the skin. Furthermore, an infectious disease is well known to include mastitis of which is inherently treatable with the composition of Mollett et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Mollett et al, discussed above and cited on enclosed PTO-892 Form, in view of newly cited Twomey et al, cited on previously enclosed PTO-1449 Form.

Claim is drawn to treating mastitis using supernatant composition.

Mollett et al teach a bacteriocin which is isolated from supernatant of a probiotic microorganism, note col. 1, lines 10-15 and col. 2, lines 20-25 and 30-36. Furthermore, the supernatant or probiotic are useful for treating pathogenic bacteria of the skin, note col. 5, lines 23-25.

Twomey et al teach treating mastitis using a bacteriocin, see pages 1981-1988.

Claim differs from Mollett et al in that mastitis is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to select the supernatant containing bacteriocin as disclosed by Mollett et al to treat mastitis as disclosed by Twomey et al because the combined prior art clearly suggest that mastitis is treatable using a bacteriocin of which is well known to be obtained from probiotic supernatant as disclosed by Mollett et al. Clearly one of skill would have been motivated to use the whole supernatant to simplify the treatment process because Mollett et al do treat that the supernatant can be used to treat skin to combat pathogenic bacteria of which cause infections such as mastitis as disclosed by Twomey et al. Clearly the claim is prima facie obvious over the cited prior

art. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed January 14, 2011, have been fully considered but they are not persuasive. The newly cited applied art clearly disclose administering and treating infections of skin and the composition is clearly anticipated by the cited prior art as disclosed and discussed above. The cited prior art composition is administered to the skin and is, therefore, adapted for administration to the skin infection, as newly recited in the claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., infusions described in the exemplified specification for treating the udders of mastitis-infected cows) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/
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Art Unit 1651